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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/697,306	10/27/2000	James F. McGuckin JR.	10546/53003	4213

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EXAMINER
DAWSON, GLENN K

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/697,306	Applicant(s) MCGUCKIN, JAMES F.	
	Examiner Glenn K Dawson	Art Unit 3761	

-- The MAILING DATE of this communication appears n the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Information Disclosure Statement

1. The information disclosure statement filed 02-19-02 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

2. The information disclosure statement filed 02-19-02 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

3. The information disclosure statement filed 02-19-02 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because of the reasons cited above. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 36-38 and 40-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuruta, et al.-5389098 in view of Sauer, et al-5562694.

4. Tsuruta discloses a stapling assembly having an anvil and stapler which can open and close, and a knife cutter. However, the grasper is not disclosed for drawing the tissue into the cutting zone.

5. Sauer discloses a cutter head and a grasper for drawing tissue into the cutting zone. It would have been obvious to have provided Tsuruta with an internal tissue grasper in order to more easily and compactly direct the desired tissue into the cutting and stapling zone.

6. Alternatively, it would have been obvious to have provided Sauer with a stapling mechanism in the head in order to effectively seal the remaining tissue following morcellation or biopsy.

7. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuruta-'098 in view of Sauer-'694 as applied to claim 36 above, and further in view of Bessler-5197649.

8. Tsuruta as modified by Sauer makes obvious the invention as claimed with the exception of the endoscope. Bessler discloses an endoscopic stapler. It would have been obvious to have provided the stapler of Tsuruta as modified by Sauer with an internal endoscope as it would have afforded the user with a means to view the surgical field and the procedure taking place.

9. Claims 44-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuruta-'098 in view of Bessler-'649.

10. Tsuruta discloses the invention as claimed with the exception of the use of an internal endoscope. Bessler discloses an endoscopic stapler. It would have been obvious to have provided the stapler of Tsuruta with an internal endoscope as it would have afforded the user with a means to view the surgical field and the procedure taking place.

11. Claims 39 and 44-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sauer, et al.-694 in view of Bessler-'649.

12. Sauer discloses the invention as claimed with the exception of the use of an internal endoscope. . Bessler discloses an endoscopic stapler. It would have been

obvious to have provided the stapler of Sauer with an internal endoscope, as it would have afforded the user with a means to view the surgical field and the procedure taking place.

4. Claims 49-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sauer, et al.-'694 in view of Kessel-DE 4006673.

5. Sauer discloses the invention as claimed with the exception of the step of advancing the head over the flexible endoscope. Kessel discloses the relative sliding of a scope and forceps. It would have been obvious to have provided Sauer with an internal scope to provide for visualization of the operative filed. To have moved the stapler over the scope would have been obvious as at some point during the procedure it obviously would be necessary to move the stapler in a distal direction in order to grasp, cut and seal additional tissue, facilitating the movement of the stapler over the scope. As shown in fig. 6, the tissue, upon grasping by the forceps, would include a folded area with two tissue portions thick.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 36-51 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 5868760 and 6264086. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims are merely broader in scope than some of those of the patents, or merely use different terms to define and claim the same elements.

Terminal Disclaimer

The terminal disclaimer was not signed.

Response to Arguments

6. Applicant's arguments filed 12-31-02 have been fully considered but they are not persuasive.

7. As the terminal disclaimer was not signed, the double patenting rejection still applies.

8. The fact that Tsuruta might disclose that the device is to be inserted through an incision is irrelevant to the rejection. Clearly, these capsules "could" be placed entirely within a body lumen, and a flexible endoscope "could" be coupled to the devices. This is all that is necessary to meet the claim limitations. The fact that these devices may be "rigid", which is a relative term (i.e.- any device has some degree of both flexibility and rigidity relative to other things) does not make them unsuitable to use with a flexible endoscope. The intended use of the device is irrelevant. In response to applicant's argument that the prior art devices are not intended for use with a flexible endoscope, a

recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). However, it should also be noted with respect to Tsuruta that on col. 34 lines 6-13, the shaft of the stapler can be either "rigid" or "flexible".

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K Dawson whose telephone number is 703-308-4304. The examiner can normally be reached on M-F 6:30-4:00, first fri. off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Weiss can be reached on 703-308-2702. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Glenn K Dawson
Primary Examiner
Art Unit 3761